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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/554,149	10/21/2005	Rinat O. Escnal	98006-26US	3257
23873 7590 06/27/2007 ROBERT W STROZIER, P.L.L.C PO BOX 429 BELLAIRE, TX 77402-0429			EXAMINER WINAKUR, ERIC FRANK	
			ART UNIT 3768	PAPER NUMBER
			MAIL DATE 06/27/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/554,149

Applicant(s)

ESENAL ET AL.

Examiner

Eric F. Winakur

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 45-81 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 45-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

## **DETAILED ACTION**

### ***Claim Objections***

1. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

The preliminary amendment filed 21 October 2005 improperly included two claims numbed 59 and two claims numbered 71.

Misnumbered claims 59 (second occurrence) - 71 (first occurrence) have been renumbered 60 - 72 and misnumbered claims 71 (second occurrence) - 79 have been renumbered 73 - 81. Applicant is requested to review the claims and update the dependencies accordingly to account for this correction.

2. Claim 69 is objected to because of the following informalities: it appears that the phrase "two transitions section" should read "two transition sections". Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 49, 50, 52 - 54, 60, 62, 64 - 66, and 69 - 81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With regard

Art Unit: 3768

to claims 49, 60, and 73, the claims do not appear to set forth a further limitation, since all radiation (as set forth in the base claims) would necessarily either be of a single wavelength (or frequency) or a plurality of wavelengths (or frequencies). With regard to claims 50, 62, and 75, since the phrase "above about 1120 nm" does not set forth an upper limit to the range, the scope of the claim is not clearly set forth. With regard to claims 52 - 54, 64 - 66, and 77 - 79, it is noted that while the claim sets forth a limitation of one element of a Markush group (exogenous substance), it is not limiting to any other members of the group. It appears that in these claims Applicant should first establish that the selected blood component is an exogenous substance, and then require that the exogenous substance has the features as set forth in the various claims. With regard to claim 69, the phrases "the radiation outlet" and "the response inlet" lack antecedent basis.

***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claims 69 - 81 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims improperly include a portion of a living being ("surface of a tissue over a big vein associated with an underside of the patient's tongue") as part of the claimed subject matter. It appears that the phrase "are proximate or in contact with" should read "are adapted to be proximate or in contact with" to avoid positively claiming the connection with the living being.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 45 - 67 are rejected under 35 U.S.C. 102(b) as being anticipated by Hatschek. Hatschek teaches an optical measurement system (Figure 4; column 6 - 8) suitable for determination of oxygen saturation from the underside of a subject's tongue (column 11, lines 41 - 64). It is inherent that at least some of the measurement light would irradiate a big vein of the subject's tongue and that the detecting step would be performed in the presence of a static (earth's) magnetic field.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claim 68 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hatschek as applied to claim 57 above, and further in view of Takeuchi et al. Hatschek teaches all of the features of the claimed invention except for a device for generating a static magnetic field. Takeuchi et al. (Figure 1 and the description thereof) teach that a device for generating a static magnetic field is required to perform magnetic resonance measurements in coordination with optical measurements of a subject. It would have been obvious to one of ordinary skill in the art at the time of the invention to implement

Art Unit: 3768

Hastchek with a device for generating a static magnetic field, as taught by Takeuchi et al., since this allows magnetic resonance measurements to be performed in addition to the optical measurements.

### ***Conclusion***

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Nielsen teach that an oximeter arrangement, such as that of Hatschek, can obtain measurements of carboxyhemoglobin by including an additional wavelength sensitive to carboxyhemoglobin in the measurement arrangement. Hoeft teaches a measurement arrangement for measuring oxygen saturation and cardiac output with use of indicator dyes such as indocyanine green. Stavridi et al. teach an optical glucose measurement device that can perform measurements from the base of a subject's tongue. Caro teaches optical measurement of analytes, including cholesterol, wherein measurements may be obtained from a subject's tongue. The prior art does not teach or suggest a measurement arrangement including a middle section interposed between two transition sections extending downwardly from each of two side sections, the middle section adapted to be proximate to or in contact with an underside of a patient's tongue that includes an emitter and receiver, in combination with the other claimed elements, for determining a concentration of a blood component and/or value of a parameter of the blood.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric F. Winakur whose telephone number is 571/272-4736. The examiner can normally be reached on M-Th, 7:30-5; alternate Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eleni Mantis-Mercader can be reached on 571/272-4740. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Eric F Winakur  
Primary Examiner  
Art Unit 3768